₽¥ [] Ü Ö 1 Ų Ł۵ æ ļ. Ŋ <u></u>å THE THE A ATTORNEY DOCKET NO.: GENE1180-2

Applicants:

Dev et al.

Continuation Application No.:

Unassigned

Continuation Application Filed:

December 14, 2001

Parent Application No.:

09/329,098

Parent Filing Date:

June 9, 1999

Page 6

REMARKS

Claims 1-6 were pending before this Preliminary Amendment as filed in the Continuation Application herein. By this Preliminary Amendment, claim 1 is amended and new claims 7-22 are added as shown in Exhibit A attached hereto to define Applicants' invention with greater particularity. No new matter is added by the amendments as the new claim language is fully supported by the Specification and original claims. Applicants submit that the claim amendments do not narrow the claims in any way within the meaning of Festo Corporation v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd., a/k/a SMC Corporation and SMC Pneumatics, Inc. 234 F.3d 558, 51 U.S.P.Q. 2d 1959 (Fed. Cir. 2000). Accordingly, claims 1-22 are currently pending.

In view of the above amendments and remarks, reconsideration and favorable action on claims 1-22 are respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date: December 14, 2001

Lisa A. Haile, J.D., Ph.D.

Registration No. 38,347

Telephone: (858) 677-1456 Facsimile: (858) 677-1465

USPTO CUSTOMER NO. 28213

GRAY CARY WARE & FREIDENRICH LLP 4365 Executive Drive, Suite 1100 San Diego, California 92121-2133 Attachment: Exhibit A

Gray Cary\GT\6269120.1 104648-156507

Applicants:

Dev et al.

Continuation Application No.:

Unassigned

Continuation Application Filed:

December 14, 2001

Parent Application No.: Parent Filing Date:

09/329,098 June 9, 1999

Exhibit A: Page 1

EXHIBIT A

Version with Markings to Show Changes Made

In the claims

Please amend claim 1 as follows:

- 1. (Amended) An apparatus for introducing a composition into at least one cell in a vessel in a subject comprising:
- a catheter having at least one inflatable balloon portion, wherein upon inflation, the balloon occludes the vessel;
- at least one infusion [passage] opening for introducing the composition into the subject proximal to the at least one inflatable balloon portion;
 - a first electrode positioned adjacent to at least one infusion opening; and
- a second electrode positioned with respect to the first electrode and the subject such that an electric field sufficient to cause electroporation of at least one cell [in the vessel is generated, thereby allowing the composition to enter at least one cell] after introduction of the composition through at least one infusion [passage] opening.

Please add new claims 7-22 as follows:

- (New) The apparatus of claim 1, wherein the catheter has two inflatable balloon portions. -- 7.
- 8. (New) The apparatus of claim 7, wherein the at least one infusion opening is between the two inflatable balloon portions.

Applicants:

Dev et al.

Continuation Application No.:

Unassigned

Continuation Application Filed:

December 14, 2001

Parent Application No.: Parent Filing Date:

09/329,098 June 9, 1999

Exhibit A: Page 2

9. (New) The apparatus of claim 1 or 8, wherein the first electrode is coincident with the at least one infusion opening.

- 10. (New) A catheter comprising:
 - a first inflatable balloon portion near the distal end of the catheter;
- a second inflatable balloon portion proximal the first inflatable balloon, wherein inflation of the first and second balloon occludes a vessel between the first and second balloon;
- at least one infusion opening for introducing a composition into a subject located between the first and second balloon portions;
- a first electrode positioned adjacent to or integral with at least one infusion opening; and a second electrode positioned with respect to the first electrode and the subject such that an electric field sufficient to cause electroporation of at least one cell before, during or after introduction of the composition through the at least one infusion opening.
- 11. (New) The catheter of claim 10, further comprising an electrical source connected to the first and second electrodes for applying a voltage between the electrodes in an amount sufficient to cause electroporation of at least one cell.
- 12. (New) The catheter of claim 10, wherein the vessel is a blood vessel.
- 13. (New) The catheter of claim 10, wherein the first electrode is formed at least in part by a biologically inert material.
- 14. (New) The catheter of claim 10, wherein the second electrode is a guidewire in the catheter.

PATENT ATTORNEY DOCKET NO.: GENE1180-2

Applicants:

Dev et al.

Continuation Application No.:

Unassigned

Continuation Application Filed:

December 14, 2001

Parent Application No.:

09/329,098

Parent Filing Date:

June 9, 1999

Exhibit A: Page 3

- 15. (New) The catheter of claim 10, wherein the second electrode is a silver plate configured to be placed in contact with the subject.
- 16. (New) The apparatus of claim 1, wherein the at least one inflatable balloon is near the distal end of the catheter.
- 17. (New) An apparatus for introducing a composition into at least one cell in a vessel in a subject comprising:
- a catheter having at least one inflatable balloon portion at a position other than the distal end of the catheter;
 - at least one infusion opening for introducing the composition into the subject;
 - a first electrode positioned adjacent to at least one infusion opening; and
- a second electrode positioned with respect to the first electrode and the subject such that an electric field sufficient to cause electroporation of at least one cell after introduction of the composition through at least one infusion passage can be administered.
- 18. (New) The catheter of claim 17, further comprising an electrical source connected to the first and second electrodes for applying a voltage between the electrodes in an amount sufficient to cause electroporation of at least one cell.
- 19. (New) The catheter of claim 17, wherein the vessel is a blood vessel.
- 20. (New) The catheter of claim 17, wherein the first electrode is formed at least in part by a biologically inert material.

PATENT ATTORNEY DOCKET NO.: GENE1180-2

Applicants:

Dev et al.

Continuation Application No.:

Unassigned

Continuation Application Filed:

December 14, 2001

Parent Application No.:

09/329,098

Parent Filing Date:

June 9, 1999

Exhibit A: Page 4

21. (New) The catheter of claim 17, wherein the second electrode is a guidewire in the catheter.

22. (New) The catheter of claim 17, wherein the second electrode is a silver plate configured to be placed in contact with the subject. –